REMARKS

In the Office Action dated February 13, 2008, claims 1-13 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. The Examiner stated that Applicants have not disclosed how the modeling of the tissue is obtained with undo experimentation. The Examiner also stated that the specification does not disclose how to obtain a three-dimensional location from a two-dimensional measurement value, as set forth in claim 9 of the present application.

This rejection is respectfully traversed for the following reasons.

In the subject matter disclosed and claimed in the present application, the tissue modeling takes place using any of numerous tissue modeling procedures. The basic concepts regarding tissue modeling are well known to those of ordinary skill in the art, and are discussed in detail beginning with the first full paragraph at page 10 of the present specification. At that location, citation is made to an article by one of the inventors relating to the use of the well known MUSIC algorithm. Much of the content of the article cited at page 10 is then duplicated or presented in the present specification through the paragraph ending in the third line from the bottom of page 12.

Therefore, not only does the present specification itself provide extensive details regarding such tissue modeling, but the present specification also cites an article by one of the inventors that describes such modeling based in even more detail, and much of the relevant information in that article is reproduced in the present specification .

Since the Examiner only made a general statement that the specification does not teach "how the modeling of the tissue is obtained without undue experimentation," Applicants are unable to determine what, if anything, is not described in the present specification that the Examiner believes a person of ordinary skill in the relevant technology would need to know in order to undertake such tissue modeling. If the Examiner can identify specific alleged deficiencies that the Examiner believes would be needed by a person of ordinary skill in the technology to model tissue, which information is not described in the present specification, the Examiner is requested to do so with specificity and Applicants will be glad to respond thereto. In view of the general nature of the alleged deficiency in the specification, however, Applicants respectfully submit that the aforementioned reference to the pages in the present specification and the article by Scholz, are more than adequate to respond to this rejection.

Similarly, in the portion of the specification immediately following the aforementioned portion that describes tissue modeling, extensive discussion is provided as to how lead fields are derived from the tissue model (even though such derivation is also described in the aforementioned Scholz article), as well as how to transform those lead fields for use with optical data, as well as how an appropriate search of the transformed lead fields is undertaken in order to find the transformed lead fields that best reproduce the information obtained from the fluoroscopic markers.

As explained in the introductory portion of the present specification, it is well known in the art to reconstruct a three-dimensional data set of a region of an examination subject based on a number of two-dimensional data sets obtained using

fluoroscopic markers. Not only are these basic concepts well known in the field of image generation using fluoroscopic markers, but they are similar to the basic concepts used in computed tomography, wherein a three-dimensional view or data set of an examination subject is obtained from a number of two-dimensional x-ray images.

As also explained in the introductory portion of the present application, such three-dimensional reconstruction based on two-dimensional data sets obtained using fluoroscopic markers is very computation-intensive and time consuming. The present inventors have the insight that expending the computing time and effort to actually reconstruct a three-dimensional image from the two-dimensional data sets obtained with the fluoroscopic markers can be forgone by comparing the information obtained using the fluoroscopic markers to tissue that is modeled so that lead fields can be derived from the model. The modeled tissue already includes three-dimensional information, and, based on the comparison result as claimed, this three-dimensional information embodied in the transformed lead fields is used to identify a three-dimensional spatial position of a lesion represented in the two-dimensional data obtained using fluoroscopic markers. This discussion begins in the last paragraph at page 12 of the present specification and occupies virtually the rest of the specification, concluding at page 21. Applicants therefore respectfully submit that the manner by which this comparison is a able to achieve a precise spatial identification of a lesion is explained in the present specification with a level of detail that clearly enables a person of ordinary skill in this field to undertake the comparison and obtain the precise three-dimensional spatial location of a lesion in question.

Again, the Examiner has only made the conclusory statement that the present specification does not provide such an enabling disclosure, but the Examiner has not identified any alleged lacking teachings or deficiencies in the present specification that the Examiner believes would be necessary for a person of ordinary skill in this field to practice the subject matter of claim 9. If the Examiner can identify such alleged deficiencies with specificity, Applicants will be glad to respond thereto, but in view of the general nature of the rejection, Applicants believe reference to the aforementioned pages in the present specification is more than adequate to respond thereto.

All claims of the application are therefore submitted to be in full compliance with all provisions of Section 112, first and second paragraphs.

Claims 1-13 also were rejected under 35 U.S.C. §103(a) as being unpatentable over Nelson et al in view of the aforementioned article by Scholz relating to the MUSIC algorithm.

Applicants respectfully traverse this rejection, but as an initial observation, Applicants believe it is inconsistent on the part of the Examiner to allege that the present specification is inadequate under Section 112, first paragraph with regard to tissue modeling using lead fields, despite the citation of the Scholz article in the present specification, while simultaneously contending that the Scholz article, in combination with the Nelson et al reference, teaches the subject matter of independent claims 1 and 13 of the present specification. In paragraph 7 of page 5 of the Office Action, the Examiner explicitly stated that the publication to Scholz teaches the method steps of modeling the tissue section and determining a set of lead fields from the model as well as transforming the lead fields. In view of the fact

that the Examiner acknowledges all of these teachings in the Scholz article, this makes the aforementioned rejection under Section 112, first paragraph even less justifiable.

As to the teachings of the Nelson et al reference, Applicants submit that the initial statement made by the Examiner, that the Nelson et al reference inherently discloses method steps to spatially localize a region in a biological tissue section, is incorrect. To the extent that the remainder of the "interpretation" of the Nelson et al reference is based on this erroneous assumption, Applicants respectfully submit that the general teachings of the Nelson et al reference are completely unrelated to the subject matter disclosed and claimed in the present application. In the Nelson et al reference, as explicitly stated at column 8, lines 18-20, a pre-dimensional image is acquired from multiple two-dimensional images respectively obtained at various viewing directions. Although Applicants do not deny that many, very different ways exist to reconstruct a three-dimensional image from multiple two-dimensional images, the Nelson et al reference itself does not provide any information as to how the aforementioned three-dimensional image is intended to be generated. No method and no reconstruction are disclosed in the Nelson et al reference for this purpose.

Moreover, as those of ordinary skill in the field of medical imaging are well aware, the reconstruction of a three-dimensional image is a completely different technique from spatial localization of a tissue region of interest. Localization methods do not necessarily require the generation of a volume image, but are only for the purpose of calculating or identifying the position of a tissue region of interest, that is to be localized, such as a tumor, with certain criteria for the location being

specified. Reconstruction techniques, by contrast, calculate a complete two or three-dimensional image of an entire region. It is possible that *after* a three-dimensional image or a two-dimensional image is reconstructed, a localization method could *then* be applied thereto, but the reconstruction of image itself has nothing whatsoever to do with localization per se.

All of the disclosures cited by the Examiner in the Nelson et al reference are no more than cumulative of the prior art discussed in the introductory portion of the present specification.

The Scholz article, as noted above, discloses generating a tissue model from which a set of lead fields can be determined. The Examiner noted that the Nelson et al reference discloses that electrical magnetic properties of various metal and diseased breast tissues exhibit wavelength dependence, and that examining the effects of tissue on other electromagnetic parameters may aid in distinguishing between various types of tissues. This is such a general and well known fact in the field of medical imaging that it was hardly necessary to rely on the Nelson et al reference as providing such a teaching. The Examiner then states that *therefore* a person of ordinary skill in the art would recognize that comparing the results from the device of Nelson et al and Scholz, breast cancer localization can be enhanced. Applicants do not find any teaching, guidance or motivation of the type necessary to substantiate a rejection under 35 U.S.C. §103(a) as being present in either of those references. The Examiner has merely cited a general, well known item of information, and attributed it to the Nelson et al reference, and then concluded that the completely different technique disclosed in the Scholz article could be used in furtherance of this general and well known information. Distinguishing between

different types of tissue is the goal of every imaging method, and every imaging method must inherently include information that allows at least two different types of tissue to be distinguished from each other, otherwise there would be no purpose in generating a medical image at all.

Applicants respectfully submit that even after the *KSR* decision, the Examiner is still required to provide more than a "therefore" clause in order to provide evidentiary support for combining the teachings of two disclosures that are so fundamentally different from each other as are the Nelson et al and Scholz references.

Only the present Applicants have had the insight to realize that, by a comparison, the three-dimensional information that is embodied in the transformed lead fields can be used to spatially identify the three-dimensional position of a lesion from data generated by fluoroscopic markers, in the manner set forth in independent claims 1 and 9. No teaching even remotely approaching that insight is present in either of the Nelson et al or Scholz references.

The respective dependent claims add further method steps, or further components, to the non-obvious combinations of claims 1 and 9, respectively. None of those dependent claims, therefore, would have been obvious to a person of ordinary skill in the field of lesion localization, under the provisions of 35 U.S.C. §103(a), based on the teachings of Nelson et al and Scholz.

In order to permit entry and consideration of this Amendment after the final rejection, an RCE is being filed simultaneously herewith.

All claims of the application are submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

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